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ORIGINAL SUBMISSION

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WORLD MINERALS

World Minerals Inc
2500 Miguelito Road
Lompoc, California 93436

October 24, 2001

RECEIVED
NOV - 6 2001
OFFICE OF
FOOD ADDITIVE SAFETY

Dr. Linda Kahl
Office of Food Additives Safety
Food and Drug Administration
200 C Street NW
Washington DC 20204

Dear Dr. Kahl:

The enclosed document notifies the United States Food and Drug Administration (FDA) of claims that particular uses of a composite filtration media are exempt from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act (the "Act") because World Minerals Inc. (the "notifier") has determined that its use as a filter aid for foods is generally recognized as safe (GRAS).

As we are aware this kind of substance is not often reviewed by the FDA, some background information is provided to assist in the review of this notification. Diatomaceous earth and perlite are both used in the filtration of food substances, and both have GRAS status. Further, these products of commerce are routinely certified to be in compliance with their respective Food Chemicals Codex monographs (see Appendix 1). The composite filtration media are made from FCC Diatomaceous Earth and FCC Perlite. Celite Corporation is a major producer of FCC Diatomaceous Earth, and Harborlite Corporation is a major producer of FCC Perlite. Celite Corporation and Harborlite Corporation are both subsidiaries of World Minerals Inc.

The composite filtration media are protected by U.S. Patent No. 5,776,353, South African Patent No. 971218, Australian Patent No. 713405, and Chinese Patent No. 66770. Other patent applications are pending worldwide. The FDA was first informed about composite filtration media in a letter dated January 12, 1998, from Timothy R. Smith of World Minerals Inc. to Dr. Alan Rulis of the FDA. At that time, only small samples of composite filtration media were available for initial testing with customers. Since that time, nearly 100 tons of composite filtration media have been manufactured in a processing facility in Lompoc, California. Commercial-scale studies of the product have been performed at a number of corn sugar processing sites in the United States and Canada, and the building of a new facility in the United States dedicated to making composite filtration media has been approved by World Minerals Board of Directors. This facility and the composite filtration media products will be operated and produced by Advanced Minerals Corporation, also a subsidiary of World Minerals Inc.

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NOTIFICATION OF GRAS DETERMINATION
FOR
COMPOSITE FILTRATION MEDIA

(c) Notifiers shall submit the following information:

(1) A claim, dated and signed by the notifier, or by the notifier's attorney or agent, or (if the notifier is a corporation) by an authorized official, that a particular use of a substance is exempt from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act because the notifier has determined that such use is GRAS.

The enclosed document notifies the United States Food and Drug Administration (FDA) of claims that particular uses of composite filtration media are exempt from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act (the "Act") because World Minerals Inc. (the "notifier") has determined that its use as a filter aid for food processing is generally recognized as safe (GRAS).

(Signature of Notifier)

(i) The name and address of notifier:

Timothy R. Smith
Vice President
World Minerals Inc.
2500 Miguelito Road
Lompoc, CA 93436

(ii) The common or usual name of the substance that is the subject of the GRAS exemption claim (i.e., the "notified substance"):

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An appropriate generic name for the notified substance is "composite filtration media." World Minerals Inc. intends to market these products under the trade name "Fluxx™ composite filtration media."

(iii) The applicable conditions of use of the notified substance, including the foods in which the substance is to be used, levels of use in such foods, and the purposes for which the substance is used, including, when appropriate, a description of the population expected to consume the substance:

The notified substance is useful as a filter aid in food processing, for a wide variety of foods. When used as a filter aid, the foods are generally in liquid form.

(iv) The basis for the GRAS determination (i.e., through scientific procedures or through experience based on common use in food).:

The principal basis of this determination for the notified substance is from scientific procedures. However, World Minerals Inc. further points out that the notified substance is a composite of two other substances already having GRAS status, namely, FCC Diatomaceous Earth and FCC Perlite, which have a long history of common use as filter aids for the processing of a wide variety of foods, food products, and various ingredients used in food products. In the United States, approximately 170,000 tons of FCC Diatomaceous Earth and 35,000 tons of FCC Perlite are currently used in the filtration of foods annually.

(v) A statement that the data and information are the basis for the notifier's GRAS determination for the Food and Drug Administration's (FDA) review and copying at reasonable times at a specific address set out in the notice or will be sent to FDA upon request.

The data and information contained herein are the basis for the notifier's GRAS determination for FDA review. Further information is available at any time by contacting the notifier at the address listed above in reply to (c)(1)(i).

(2) Detailed information about the identity of the notified substance, including, as applicable, its chemical name, Chemical Abstracts Service (CAS) Registry Number, Enzyme Commission number, empirical formula, structural formula, quantitative composition, method of manufacture (excluding any trade secrets and including, for substances of natural biological origin, source information such as genus and species), characteristic properties, any content of potential human toxicants, and specifications for food-grade material;

Notified Product Description

The notified substance is a composite of FCC Diatomaceous Earth and FCC Perlite thermally sintered in the presence of an alkali metal flux, such as soda ash (*i.e.*, sodium carbonate, Na_2CO_3). Its usefulness as a filter aid results from the microstructural complexity of its components, FCC Diatomaceous Earth and FCC Perlite, further made into complex sintered, agglomerated particles. A scanning electron micrograph (Figure 1) of the notified substance shows these features:

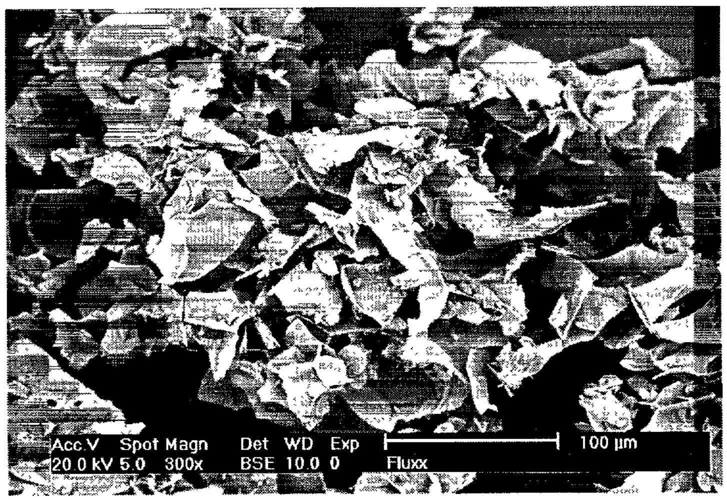

Figure 1. Scanning Electron Micrograph of the Notified Substance, Composite Filtration Media

To better understand the nature of the notified substance, some background on the components is useful. FCC Diatomaceous Earth consists of the processed siliceous skeletons (also known as frustules or shells) of diatoms. Diatoms are a diverse array of microscopic, single-celled golden brown algae of the class Bacillariophyceae, in which the cytoplasm is contained within ornate siliceous frustules of varied and intricate structure. These frustules are sufficiently durable to retain much of their porous structure virtually intact through long periods of geologic time when preserved in conditions that maintain chemical equilibrium. The commercial source of diatom skeletons is from sedimentary deposits, hence the name "diatomaceous earth." The frustules are composed primarily of amorphous silica (*i.e.*, silicon dioxide, SiO_2), and are virtually insoluble in water, in acids (except hydrofluoric acid and, to a much lesser extent, phosphoric acid), and dilute alkalis.

FCC Diatomaceous Earth is commonly divided into three groups: natural powder, calcined powder, and flux-calcined powder. The type of FCC Diatomaceous Earth used as feed to make the notified substance is of the natural powder variety, which means that it has been dried in air and classified by particle size. Figure 2 shows some typical microstructural features of an FCC Diatomaceous Earth used to make the notified substance. While soluble chemistry is important to safety, FCC Diatomaceous Earth may

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be somewhat variable in its bulk chemistry, but usually has a chemical constitution of not less than approximately 88% SiO_2, with the remainder consisting of various concentrations of aluminum, iron, sodium, potassium, calcium, and small concentrations of metallic elements. FCC Diatomaceous Earth is often used where a high degree of clarification is needed or desired.

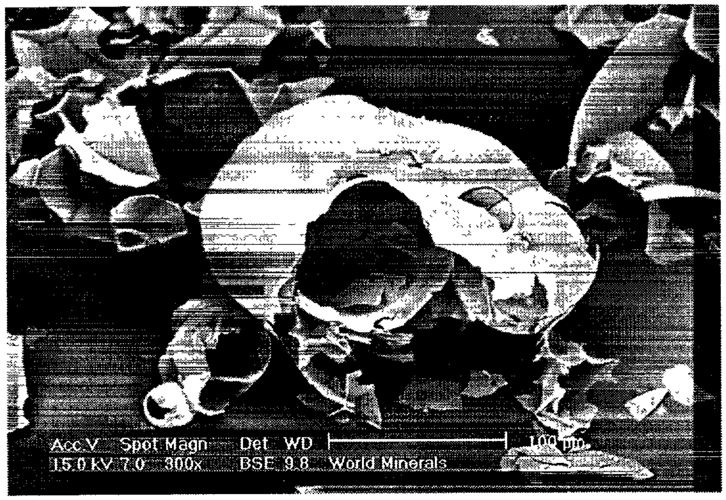

Figure 2. Scanning Electron Micrograph of FCC Perlite

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Typically, as more FCC Diatomaceous Earth replaces FCC Perlite in a particular feed formulation of the notified substance, the filtration properties are modified such that the resulting composite filter aid usually offers greater clarifying capability, but at the expense of reduced throughput of liquid. Thus, a formulation containing 25 parts of FCC Diatomaceous Earth to 75 parts of FCC Perlite clarifies better than a formulation containing 10 parts of the same FCC Diatomaceous Earth to 90 parts of the same FCC Perlite, but the filtration also takes place at a reduced rate.

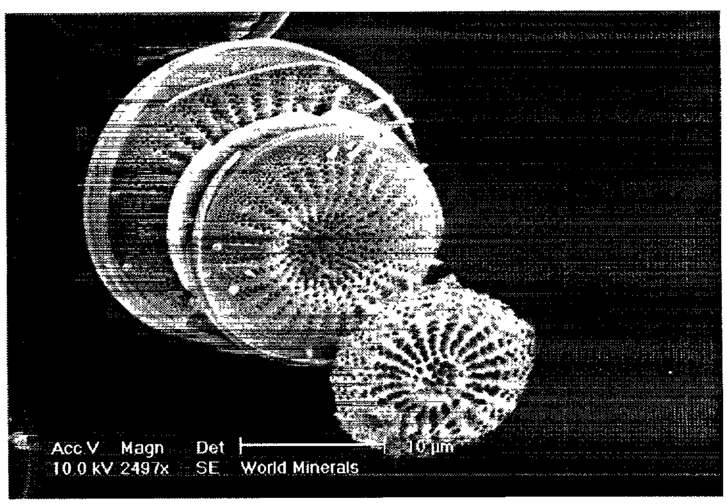

Figure 3. Scanning Electron Micrograph of FCC Diatomaceous Earth

The useful proportion of FCC Diatomaceous Earth in a feed to make composite filtration media can range from less than 1% to 80% or more; FCC Perlite can range from 99% to less than 20%; an alkali metal flux such as soda ash can be added from less than 1% to over 8%. As is clearly evident, since the basic chemistry of FCC Diatomaceous Earth and FCC Perlite are different and the proportions vary for different grades of the notified substance, ordinarily this is not a particularly useful measure of the material.

Samples for Study

At this time, the results of a World Minerals market study suggest that the most common grade of the notified substance will have a feed composition of approximately 88.4% FCC Perlite, approximately 4.7% FCC Diatomaceous Earth and approximately 6.9% soda ash. Representative samples of three separate lots of the notified substance having this composition were obtained from a sample production operation located in Lompoc, California. The lots were identified as shown in Table 1, below:

Table 1. Lot Identification

Lot Number	Sample Identification	Production Date
1	F55-ZS-CP3-149	May 23, 2000
2	F55-ZS-CP4-442	August 3, 2000
3	F55-ZS-CP4-887	August 8, 2000

Chemical Composition

The bulk chemical composition of the samples was determined by wavelength-dispersive x-ray fluorescence. A Philips 2404 spectrometer was used, with calculations performed using Uniquant® software provided by Philips. Depending on the selected composite formulation for the notified substance, the bulk chemical composition can vary widely. Results for the three sample lots are provided in Table 2, below, to give an idea of what may be expected from a typical analysis. However, we again caution that this type of chemical analysis is not particularly useful for defining a composite substance in which the individual component concentrations intentionally vary.

Table 2. Chemical Composition of Lot Samples

Element Determined	Units	Lot 1	Lot 2	Lot 3
Silicon	%(w/w) SiO_2	71.40	71.16	71.40
Aluminum	%(w/w) Al_2O_3	13.02	13.38	13.30
Sodium	%(w/w) Na_2O	8.66	8.32	8.55
Potassium	%(w/w) K_2O	4.97	4.70	4.48
Iron	%(w/w) Fe_2O_3	0.67	0.60	0.58
Calcium	%(w/w) CaO	0.53	0.48	0.49
Sulfur	%(w/w) SO_3	0.53	0.46	0.40
Magnesium	%(w/w) MgO	0.11	0.14	0.15
Titanium	%(w/w) TiO_2	0.11	0.09	0.09
Phosphorus	%(w/w) P_2O_5	0.01	0.01	0.01
Total	%(w/w)	100.01	99.34	99.45

General Properties Testing

Some properties are useful to compare the notified substance with its relatives, FCC Diatomaceous Earth and FCC Perlite. The methods are straightforward as follows:

Loss on Drying. Dry at 105 °C for 2 hours.
Loss on Ignition. Weigh accurately about 1 g of a previously dried sample, and ignite at 800 °C to constant weight.

pH. Boil 10.0 g of a sample with 100 mL of deionized water for 30 minutes, make up to 100 mL and filter with Whatman GF/C filter paper. Measure the pH.

The results are compared with the limits of FCC Diatomaceous Earth and FCC Perlite in Table 3, below.

Table 3. General Properties

Sample or Specification	*Loss on Drying, % (w/w)*	*Loss on Ignition, % (w/w)*	*pH, standard pH units*
Lot 1	0.36	0.96	10.89
Lot 2	0.12	0.66	10.17
Lot 3	0.31	0.52	10.65
FCC Perlite Specification	not more than 3.0	not more than 7.0	between 5 and 11
FCC Diatomaceous Earth Specification, natural powders	not more than 10.0	not more than 7.0	between 5 and 11
FCC Diatomaceous Earth Specification, calcined and flux-calcined powders	not more than 3.0	not more than 0.5	between 5 and 11

We note that the loss on drying is quite low when compared with FCC perlite and FCC Diatomaceous Earth natural powders. Loss on ignition is somewhat greater than that FCC Diatomaceous Earth calcined and flux-calcined powders for the lots tested. This particular formulation represents a typical result expected at the low end of the range of sintering temperatures useful for making the notified substance; thus, the loss on ignition values are greater than for FCC Diatomaceous Earth calcined and flux-calcined powders for this formulation. Formulations containing less FCC Perlite in the feed are sintered at higher temperature and would thus be expected to have somewhat lower loss on ignition.

Testing for Soluble Arsenic and Lead

Arsenic and lead were extracted essentially according to the protocol established for FCC monographs for Perlite and Diatomaceous Earth, in which a 10.0 g sample is weighed into a 250 mL Erlenmeyer flask, to which 50 mL of 0.5-N hydrochloric acid are added. The flask opening is covered with parafilm and shaken at 100 rpm for 15 minutes in a water bath maintained at 70 °C. The solution is cooled and filtered through Whatman No. 3 filter paper into a 100 mL volumetric flask. The slurry is washed with three 10 mL portions of hot (70 °C) deionized water, the washes combined with the filtrate, and diluted to the mark with deionized water. Arsenic and lead in the extract are then determined with instrumental detection by inductively-coupled argon plasma spectrophotometry (ICP) using a Fison 1310+ instrument. Results for the three lots are provided in Table 4, below, and compared with the limits for FCC Perlite and FCC Diatomaceous Earth.

Table 4. Arsenic and Lead

Sample or Specification	*Arsenic (mg As/kg sample)*	*Lead (mg Pb/kg sample)*
Lot 1	0.5	1.9
Lot 2	0.2	0.3
Lot 3	0.4	0.5
FCC Perlite Specification	not more than 10 mg/kg	not more than 10 mg/kg
FCC Diatomaceous Earth Specification	not more than 10 mg/kg	not more than 10 mg/kg

Testing for Element Solubility in an Aqueous Ethanol Solvent

To determine to what degree some other trace elements may be solubilized, 5.0 g lot samples were extracted in 100 mL of a 10% aqueous ethanol solution at 40 °C for ten days. The mixture was then filtered through a 0.2 µm membrane filter, the filtrate collected and made up to 100 mL with deionized water. Elemental determinations were performed by Elemental Research, Inc. (Vancouver, Canada), using ionization in an inductively-coupled argon plasma coupled with a mass spectrometer detector (ICP-MS). The extractions and determinations were performed in triplicate for each lot sample. The blank-corrected results are shown in Tables 5a, 5b, and 5c, below, with units referring to mg soluble element per kilogram of sample (*i.e.*, parts per million).

Table 5a. Soluble Elements, Lot 1

Element	Units	Result 1	Result 2	Result 3	Mean	Standard Deviation (±)
Lithium	mg Li/kg	0.46	0.46	0.47	0.46	0.01
Beryllium	mg Be/kg	<0.01	<0.01	<0.01	<0.01	< 0.01
Boron	mg B/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Sodium	mg Na/kg	5418	5058	4998	5158	227
Magnesium	mg Mg/kg	3.9	4.0	4.7	4.2	0.4
Aluminum	mg Al/kg	20.2	12.6	19.8	17.5	4.3
Silicon	mg Si/kg	722	802	882	802	80
Phosphorus	mg P/kg	1.4	1.6	2.2	1.7	0.4
Potassium	mg K/kg	164	143	147	151	11
Calcium	mg Ca/kg	9.4	9.8	10.8	10.0	0.7
Scandium	mg Sc/kg	0.18	0.18	0.17	0.18	< 0.01
Titanium	mg Ti/kg	0.30	0.28	0.31	0.30	0.02
Vanadium	mg V/kg	1.24	1.22	1.18	1.21	0.03
Chromium	mg Cr/kg	0.38	0.54	0.48	0.47	0.08
Manganese	mg Mn/kg	0.65	0.62	0.65	0.64	0.02
Iron	mg Fe/kg	2.8	2.9	3.2	3.0	0.2
Cobalt	mg Co/kg	0.01	<0.01	<0.01	0.01	<0.01
Nickel	mg Ni/kg	0.02	0.02	0.01	0.01	0.01
Copper	mg Cu/kg	0.02	0.02	0.02	0.02	<0.01
Zinc	mg Zn/kg	<0.01	0.12	0.06	0.05	0.07
Gallium	mg Ga/kg	0.04	0.04	0.04	0.04	<0.01
Germanium	mg Ge/kg	0.01	0.01	<0.01	0.01	<0.01
Arsenic	mg As/kg	0.22	0.22	0.26	0.23	0.02
Selenium	mg Se/kg	0.04	0.02	0.04	0.03	0.01
Rubidium	mg Rb/kg	0.09	0.08	0.08	0.08	<0.01
Strontium	mg Sr/kg	0.04	0.05	0.05	0.05	<0.01
Yttrium	mg Y/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Zirconium	mg Zr/kg	0.01	0.01	0.01	0.01	<0.01
Niobium	mg Nb/kg	0.02	0.01	0.02	0.01	<0.01
Molybdenum	mg Mo/kg	0.27	0.27	0.26	0.26	<0.01
Ruthenium	mg Ru/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Rhodium	mg Rh/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Palladium	mg Pd/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Silver	mg Ag/kg	<0.01	0.01	0.01	<0.01	<0.01
Cadmium	mg Cd/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Tin	mg Sn/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Antimony	mg Sb/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Tellurium	mg Te/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Cesium	mg Cs/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Barium	mg Ba/kg	0.05	0.04	0.04	0.04	<0.01
Lanthanum	mg La/kg	0.01	0.01	0.01	0.01	<0.01
Cerium	mg Ce/kg	0.01	0.01	0.01	0.01	<0.01
Praseodymium	mg Pr/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Neodymium	mg Nd/kg	0.01	<0.01	<0.01	<0.01	<0.01
Samarium	mg Sm/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Europium	mg Eu/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Gadolinium	mg Gd/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Terbium	mg Tb/kg	<0.01	<0.01	<0.01	<0.01	<0.01

Dysprosium	mg Dy/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Holmium	mg Ho/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Erbium	mg Er/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Thulium	mg Tm/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Ytterbium	mg Yb/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Lutetium	mg Lu/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Hafnium	mg Hf/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Tantalum	mg Ta/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Tungsten	mg W/kg	0.05	0.03	0.03	0.04	0.01
Rhenium	mg Re/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Iridium	mg Ir/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Platinum	mg Pt/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Gold	mg Au/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Mercury	mg Hg/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Thallium	mg Tl/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Lead	mg Pb/kg	0.01	0.01	0.01	0.01	<0.01
Bismuth	mg Bi/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Thorium	mg Th/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Uranium	mg U/kg	0.01	0.01	0.01	0.01	<0.01

Table 5b. Soluble Elements, Lot 2

Element	Units	Result 1	Result 2	Result 3	Mean	Standard Deviation (±)
Lithium	mg Li/kg	0.09	0.09	0.08	0.09	0.004
Beryllium	mg Be/kg	<0.01	<0.01	<0.01	<0.01	< 0.01
Boron	mg B/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Sodium	mg Na/kg	1108	1054	1078	1080	27
Magnesium	mg Mg/kg	<0.1	<0.1	0.1	<0.1	<0.1
Aluminum	mg Al/kg	18.6	15.6	19.3	17.8	2.0
Silicon	mg Si/kg	462	462	502	475	23
Phosphorus	mg P/kg	1.0	1.2	1.2	1.1	0.1
Potassium	mg K/kg	53	51	53	52	1
Calcium	mg Ca/kg	19.6	22.2	21.4	21.1	1.3
Scandium	mg Sc/kg	0.08	0.08	0.09	0.09	0.01
Titanium	mg Ti/kg	0.02	0.01	0.02	0.02	<0.01
Vanadium	mg V/kg	1.48	1.44	1.48	1.47	0.02
Chromium	mg Cr/kg	0.32	0.28	0.36	0.32	0.04
Manganese	mg Mn/kg	0.01	<0.01	0.01	0.01	<0.01
Iron	mg Fe/kg	0.2	0.2	0.1	0.2	<0.01
Cobalt	mg Co/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Nickel	mg Ni/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Copper	mg Cu/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Zinc	mg Zn/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Gallium	mg Ga/kg	0.04	0.04	0.04	0.04	<0.01
Germanium	mg Ge/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Arsenic	mg As/kg	0.14	0.08	0.12	0.11	0.03
Selenium	mg Se/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Rubidium	mg Rb/kg	0.04	0.04	0.04	0.04	<0.01
Strontium	mg Sr/kg	0.07	0.07	0.07	0.07	<0.01
Yttrium	mg Y/kg	<0.01	<0.01	<0.01	<0.01	<0.01

Zirconium	mg Zr/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Niobium	mg Nb/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Molybdenum	mg Mo/kg	0.24	0.24	0.23	0.24	<0.01
Ruthenium	mg Ru/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Rhodium	mg Rh/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Palladium	mg Pd/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Silver	mg Ag/kg	0.01	0.01	0.01	<0.01	<0.01
Cadmium	mg Cd/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Tin	mg Sn/kg	<0.01	0.09	<0.01	<0.03	0.05
Antimony	mg Sb/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Tellurium	mg Te/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Cesium	mg Cs/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Barium	mg Ba/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Lanthanum	mg La/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Cerium	mg Ce/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Praseodymium	mg Pr/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Neodymium	mg Nd/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Samarium	mg Sm/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Europium	mg Eu/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Gadolinium	mg Gd/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Terbium	mg Tb/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Dysprosium	mg Dy/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Holmium	mg Ho/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Erbium	mg Er/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Thulium	mg Tm/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Ytterbium	mg Yb/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Lutetium	mg Lu/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Hafnium	mg Hf/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Tantalum	mg Ta/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Tungsten	mg W/kg	0.03	0.03	0.03	0.03	<0.01
Rhenium	mg Re/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Iridium	mg Ir/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Platinum	mg Pt/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Gold	mg Au/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Mercury	mg Hg/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Thallium	mg Tl/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Lead	mg Pb/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Bismuth	mg Bi/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Thorium	mg Th/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Uranium	mg U/kg	<0.01	<0.01	<0.01	<0.01	<0.01

Table 5c. Soluble Elements, Lot 3

Element	Units	Result 1	Result 2	Result 3	Mean	Standard Deviation (±)
Lithium	mg Li/kg	0.34	0.37	0.36	0.35	0.01
Beryllium	mg Be/kg	<0.01	<0.01	<0.01	<0.01	< 0.01
Boron	mg B/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Sodium	mg Na/kg	3138	3398	3218	3251	133
Magnesium	mg Mg/kg	7.0	7.4	7.4	7.3	0.2
Aluminum	mg Al/kg	33.2	35.4	32.6	33.7	1.5

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Silicon	mg Si/kg	862	982	942	929	61
Phosphorus	mg P/kg	2.8	2.8	6.4	3.0	0.3
Potassium	mg K/kg	109	117	110	112	5
Calcium	mg Ca/kg	14.4	14.6	13.0	14.0	0.9
Scandium	mg Sc/kg	0.17	0.16	0.15	0.16	0.01
Titanium	mg Ti/kg	0.30	0.29	0.28	0.29	0.01
Vanadium	mg V/kg	1.58	1.72	1.66	1.65	0.07
Chromium	mg Cr/kg	0.54	0.56	0.54	0.55	0.01
Manganese	mg Mn/kg	0.59	0.58	0.57	0.58	0.01
Iron	mg Fe/kg	1.9	2.2	2.0	2.0	0.1
Cobalt	mg Co/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Nickel	mg Ni/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Copper	mg Cu/kg	0.01	0.01	<0.01	0.01	<0.01
Zinc	mg Zn/kg	0.06	<0.01	<0.01	0.01	<0.01
Gallium	mg Ga/kg	0.04	0.05	0.04	0.04	<0.01
Germanium	mg Ge/kg	<0.01	<0.01	0.01	0.01	<0.01
Arsenic	mg As/kg	0.16	0.12	0.08	0.12	0.04
Selenium	mg Se/kg	0.04	0.04	<0.01	0.03	0.02
Rubidium	mg Rb/kg	0.06	0.07	0.06	0.07	<0.01
Strontium	mg Sr/kg	0.05	0.06	0.05	0.05	<0.01
Yttrium	mg Y/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Zirconium	mg Zr/kg	0.01	0.01	0.01	0.01	<0.01
Niobium	mg Nb/kg	0.02	0.02	0.02	0.02	<0.01
Molybdenum	mg Mo/kg	0.24	0.26	0.25	0.25	0.01
Ruthenium	mg Ru/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Rhodium	mg Rh/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Palladium	mg Pd/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Silver	mg Ag/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Cadmium	mg Cd/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Tin	mg Sn/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Antimony	mg Sb/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Tellurium	mg Te/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Cesium	mg Cs/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Barium	mg Ba/kg	0.02	0.02	0.02	0.02	<0.01
Lanthanum	mg La/kg	0.01	<0.01	<0.01	<0.01	<0.01
Cerium	mg Ce/kg	0.01	0.01	0.01	0.01	<0.01
Praseodymium	mg Pr/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Neodymium	mg Nd/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Samarium	mg Sm/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Europium	mg Eu/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Gadolinium	mg Gd/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Terbium	mg Tb/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Dysprosium	mg Dy/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Holmium	mg Ho/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Erbium	mg Er/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Thulium	mg Tm/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Ytterbium	mg Yb/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Lutetium	mg Lu/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Hafnium	mg Hf/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Tantalum	mg Ta/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Tungsten	mg W/kg	0.03	0.03	0.03	0.03	<0.01
Rhenium	mg Re/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Iridium	mg Ir/kg	<0.01	<0.01	<0.01	<0.01	<0.01

Platinum	mg Pt/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Gold	mg Au/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Mercury	mg Hg/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Thallium	mg Tl/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Lead	mg Pb/kg	0.01	0.01	0.01	0.01	<0.01
Bismuth	mg Bi/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Thorium	mg Th/kg	<0.01	<0.01	<0.01	<0.01	<0.01
Uranium	mg U/kg	<0.01	<0.01	<0.01	<0.01	<0.01

To evaluate the quality of data reported in Tables 5a, 5b, and 5c, spiking and recovery tests were performed for selected elements on the extract from Lot 3, and recoveries were also compared with known values of selected elements for a known reference material. A certified standard reference material, NBS 1643D "Trace Elements in Water," was obtained from the National Institute of Standards and Technology, Maryland. This data is supplied in Appendix 2 in tables 7, 8a, 8b, and 8c.

Crystalline Silica

Crystalline silica has been determined to be a probable human carcinogen according to IARC. In the United States, materials having concentrations greater than 0.1 %(w/w) total respirable crystalline silica require a warning label to this effect. At present, this limit is at the detection limit of the best mode of analysis, which is by quantitative x-ray diffraction spectrometry. FCC Diatomaceous Earth, especially calcined and flux calcined varieties, but sometimes also natural varieties as well, often contains detectable concentrations of crystalline silica. Two varieties of crystalline silica are generally found – quartz and cristobalite. Quartz is naturally found in some diatomite deposits and is usually difficult to remove in conventional processing. Cristobalite is usually absent from diatomite deposits, but often readily forms on high-temperature processing. For some deposits, quartz sometimes forms for calcined products instead. Most FCC Perlite sold in the United States does not have crystalline silica, but also does not offer the clarifying efficiency of FCC Diatomaceous Earth.

A particular advantage of the notified substance is that it can be formulated with FCC Diatomaceous Earth and FCC Perlite known to be low in quartz. With a lower sintering temperature than is usually used for calcining or flux calcining FCC Diatomaceous Earth, composite filtration media can be made that offer high clarification efficiency, but are comparatively low in concentration of crystalline silica. Results for three lots are shown in Table 6, following, as determined by quantitative x-ray diffraction spectrometry:

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Table 6. Determination of Crystalline Silica

Sample	*Quartz [%(w/w)]*	*Cristobalite [%(w/w)]*
Lot 1	< 0.1	< 0.1
Lot 2	< 0.1	< 0.1
Lot 3	< 0.1	< 0.1

Recommended Specifications for Food Grade Composite Filtration Media

The recommended specifications for the "food grade" f the notified substance composite filtration media are as follows:

Description: a light gray, pink, or white powder consisting of composite particles of FCC Diatomaceous Earth and FCC perlite sintered in air at 1300 – 1900 °F in the presence of an alkali metal flux such as sodium carbonate.

Functional Use in Foods: filter aid in food processing.

Arsenic: not more than 10 mg As/kg.
Lead: not more than 5 mg Pb/kg.
Loss on Drying: not more than 3%.
Loss on Ignition: not more than 7%.
pH: between 5 and 11.

Further Descriptions

Based on the above information, the notified substance is chemically considered to belong to the group whose members are known as glass oxides. Along with several other glass oxides that may differ from the notified substance, the Chemical Abstracts Service (CAS) registry number for this broad group of substances is 65997-17-3.

As aforementioned, the bulk chemical composition of the notified substance may vary to some degree without adversely affecting its function or use as a filter aid for food processing. However, a general chemical formula may be stated as (Na, K, Al)SiO_2, in a manner analogous to chemical descriptions of many mineral substances that vary in chemical composition.

(3) Information on any self-limited levels of use;

The notified substance is not generally useful for filtration of foods except in slurry form. Because of the high porosity of composite filtration media, liquid absorption is relatively high compared to many materials. Therefore, the practical maximum limit of contact is usually approximately 25 %(w/v) of composite filtration media in a liquid foodstuff having a viscosity like that of water. Concentrations greater than this value, or in liquids of significantly greater viscosity, are usually too thick to allow fluid to flow through the media except under extraordinary pressures. In ordinary practice, concentrations much lower than this are used. In fact, the lowest concentration that provides reasonably good filtration performance is usually used. A typical concentration is often in the range of 0.5 to 5 %(w/v).

and (4) A detailed summary of the basis for the notifier's determination that a particular use of the notified substance is exempt from the premarket approval requirements of the act because such use is GRAS. Such determination may be base either on scientific procedures or common use in food.

(i) For a GRAS determination through scientific procedures, such summary shall include:

(A) A comprehensive discussion of, and citations to, generally available and accepted scientific data, information, methods, or principles that the notifier relies on to establish safety, including a consideration of the probable consumption of the substance formed in or on food because of its use and the cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substances in such diet.

The notified substance, *i.e.*, composite filtration media prepared from FCC Diatomaceous Earth and FCC Perlite thermally sintered in the presence of an alkali metal flux, such as soda ash, is exempt from the premarket approval requirements of the act because such use as a filter aid in food processing is GRAS. For making this review, we rely on the existing FCC monographs (Food Chemicals Codex IV, see Appendix 1 accompanying this document) for FCC Diatomaceous Earth and FCC Perlite. These substances are clearly related materially to the notified substance, and we note that in the United States approximately 170,000 tons of FCC Diatomaceous Earth and 35,000 tons of FCC Perlite are currently used in the filtration of foods annually.

The microstructural features of FCC Diatomaceous Earth and FCC Perlite are largely preserved in preparing the notified substance, such that the main part of the present GRAS determination is based on chemical testing conducted in a manner analogous to that of its components. No unexpected results are observed. Arsenic and lead values are low and within the limits for FCC Diatomaceous Earth and FCC Perlite when tested by the FCC extraction method. Similar to FCC Diatomaceous Earth and FCC Perlite, the pH of an aqueous slurry is neither excessively acidic or alkaline, and loss on drying and loss on ignition are also within expected ranges.

At the temperatures of sintering, typically 1300 – 1900 °F, any organic matter is destroyed. Thus, additional testing for organic constituents is unnecessary.

Additional data was obtained, however, to determine if any other trace inorganic elements were present upon aggressive extraction in an aqueous ethanol solution. Some common elements (sodium, calcium, *etc.*) were detected, much as expected. However, toxic or heavy elements were either absent or detected in such extremely low concentrations that they are not of concern to the use of the notified substance as a filter aid in food processing.

(B) A comprehensive discussion of any reports of investigations or other information that may appear to be inconsistent with the GRAS determination;

To the best of our knowledge, there are no reports of investigations or information inconsistent with this GRAS determination.

(C) The basis for concluding, in light of the data and information described under paragraphs (c)(1), (c)(2), (c)(3), (c)(4)(i)(A), and (c)(4)(i)(B) of this section, that there is consensus among experts qualified by scientific training and experience to evaluate the safety of substances added to food that there is reasonable certainty that the substance is not harmful under the intended conditions of use.

The long and safe history of use of FCC Diatomaceous Earth and FCC Perlite as filter aids in food processing reasonably concludes the notified substance, which is essentially a composite of these two substances, shall also not be harmful as a filter aid in food processing. Additional testing provided in (c)(2) fully supports this conclusion.

(ii) For a GRAS determination through experience based on common use in food, such summary shall include:

(A) A comprehensive discussion of, and citations to, generally available data and information that the notifier relies on to establish safety, including evidence of a substantial history of consumption of the substance by a significant number of consumers;

(B) A comprehensive discussion of any reports of investigations or other information that may appear to be inconsistent with the GRAS determination;

(C) The basis for concluding, in light of the data and information described under paragraphs (c)(1), (c)(2), (c)(3), (c)(4)(ii)(A), and (c)(4)(ii)(B) of this section, that there is consensus among experts qualified by scientific training and experience to evaluate the safety of substances added to food that there is reasonable certainty that the substance is not harmful under the intended conditions of use.

While the notified substance proper has been successfully used by a significant number of consumers without incident, particularly in filtration of a variety of corn sugar products such as high-fructose corn syrup and maltodextrin, this information is not expected to be formally reported. Nevertheless, there are no known reports of investigations or information inconsistent with this GRAS determination. Again, we point out that the notified substance is closely and materially related to FCC Diatomaceous Earth and FCC Perlite; in the United States approximately 170,000 tons of

FCC Diatomaceous Earth and 35,000 tons of FCC Perlite are currently used in the filtration of foods annually.

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We look forward to your review of this Notification, and would be pleased to answer any questions you may have by contacting the notifier at the address provided in (1)(i), or by telephone at 805 737 1364, by fax at 805 737 1363, or by electronic mail at smitht@worldminerals.com .

Sincerely,

Timothy R. Smith
Vice President
Research and Development
World Minerals Inc.

Appendix 1.

Food Chemicals Codex IV

Monographs
for
Diatomaceous Earth
and
Perlite

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PAGES 000021-000024 HAVE BEEN REMOVED IN ACCORDANCE WITH COPYRIGHT LAWS
PLEASE SEE APPENDED BIBLIOGRAPHY FOR A LIST OF THE REFERENCES THAT
HAVE BEEN REMOVED FROM THIS REQUEST

Appendix 2.

Results of Recovery Tests
in
Quantitative Analysis

Table 7. Recovery Tests of Selected Elements in NBS 1643D

Element	Units (parts per billion)	Concentration Found	Reference Value	% Recovery
Lithium	µg Li/kg	15.9	16.5	96.4
Beryllium	µg Be/kg	13.4	12.5	107
Boron	µg B/kg	165	145	114
Sodium	µg Na/kg	22500	22100	100
Magnesium	µg Mg/kg	7600	7990	95.1
Aluminum	µg Al/kg	115	128	90
Silicon	µg Si/kg	2810	3000	100
Potassium	µg K/kg	2390	2360	100
Calcium	µg Ca/kg	30300	31000	100
Vanadium	µg V/kg	35	35	100
Chromium	µg Cr/kg	18	19	97
Manganese	µg Mn/kg	37.4	37.7	99.3
Iron	µg Fe/kg	70	90	80
Cobalt	µg Co/kg	24.7	25	98.8
Nickel	µg Ni/kg	60.4	58.1	104
Copper	µg Cu/kg	21	21	104
Zinc	µg Zn/kg	87	72	120
Arsenic	µg As/kg	57	56	102
Selenium	µg Se/kg	11	11	96
Strontium	µg Sr/kg	375	295	127
Molybdenum	µg Mo/kg	114	113	101
Silver	µg Ag/kg	0.94	1.27	74
Cadmium	µg Cd/kg	6.3	6.5	98
Antimony	µg Sb/kg	56.6	54.1	105
Barium	µg Ba/kg	571	507	113
Thallium	µg Tl/kg	7.12	7.28	97.8
Lead	µg Pb/kg	17.9	18.2	98.6

Table 8a. Lot 3 Spiking and Recovery Tests at 0.5 mL spiking

Element	Units	Lot 3 without spike	Lot 3 with spike	Concentration Found	Spike Concentration	% Recovery
Titanium	µg Ti/kg	6.2	17.5	11.3	10	113
Vanadium	µg V/kg	92	283	191	200	96
Chromium	µg Cr/kg	66	120	54	50	108
Manganese	µg Mn/kg	17.4	78.1	60.7	50	121
Cobalt	µg Co/kg	<0.1	4.6	4.7	5	94
Nickel	µg Ni/kg	0.3	5.3	5.0	5	100
Copper	µg Cu/kg	1.4	11.1	9.7	10	97
Zinc	µg Zn/kg	2	52	50	50	100
Gallium	µg Ga/kg	2.6	4.8	2.2	2.5	88
Arsenic	µg As/kg	11	145	134	100	134
Rubidium	µg Rb/kg	3.4	182	178.7	200	89.3
Strontium	µg Sr/kg	3.2	97.9	94.7	100	94.7
Zirconium	µg Zr/kg	0.6	4.6	4.0	5	79.8
Cadmium	µg Cd/kg	<0.1	2.3	2.3	2.5	91.6
Tin	µg Sn/kg	0.1	4.6	4.5	5	89.6
Barium	µg Ba/kg	1.1	40.5	39.5	50	78.9
Mercury	µg Hg/kg	<0.1	2.4	2.4	2.5	96
Lead	µg Pb/kg	0.3	3.4	3.1	2.5	125.6

Table 8b. Lot 3 Spiking and Recovery Tests at 1.0 mL spiking

Element	Units	Lot 3 without spike	Lot 3 with spike	Concentration Found	Spike Concentration	% Recovery
Titanium	µg Ti/kg	6.2	27.8	21.6	20	108
Vanadium	µg V/kg	92	740	648	400	162
Chromium	µg Cr/kg	66	154	88	100	88
Manganese	µg Mn/kg	17.4	128.0	110.6	100	111
Cobalt	µg Co/kg	<0.1	8.8	8.9	10	89
Nickel	µg Ni/kg	0.3	9.8	9.5	10	95
Copper	µg Cu/kg	1.4	20.1	18.7	20	94
Zinc	µg Zn/kg	2	99	97	100	97
Gallium	µg Ga/kg	2.6	7.0	4.4	5	88
Arsenic	µg As/kg	11	274	263	200	132
Rubidium	µg Rb/kg	3.4	511	508	400	127
Strontium	µg Sr/kg	3.2	269	266	200	133
Zirconium	µg Zr/kg	0.6	10.7	10.1	10	101
Cadmium	µg Cd/kg	<0.1	4.2	4.2	5	83
Tin	µg Sn/kg	0.1	8.8	8.7	10	87
Barium	µg Ba/kg	1.1	76.1	75.1	100	75
Mercury	µg Hg/kg	<0.1	3.6	3.6	5	72
Lead	µg Pb/kg	0.3	6.4	6.1	5	121.4

Table 8c. Lot 3 Spiking and Recovery Tests at 2.0 mL spiking

Element	Units	Lot 3 without spike	Lot 3 with spike	Concentration Found	Spike Concentration	% Recovery
Titanium	µg Ti/kg	6.2	44.4	38.2	40	96
Vanadium	µg V/kg	92	1260	1168	800	146
Chromium	µg Cr/kg	66	233	167	200	84
Manganese	µg Mn/kg	17.4	212	195	200	97
Cobalt	µg Co/kg	<0.1	16.2	16.3	20	82
Nickel	µg Ni/kg	0.3	17.7	17.4	20	87
Copper	µg Cu/kg	1.4	36.7	35.3	40	88
Zinc	µg Zn/kg	2	184	182	200	91
Gallium	µg Ga/kg	2.6	10.7	8.1	10	81
Arsenic	µg As/kg	11	559	548	400	137
Rubidium	µg Rb/kg	3.4	955	952	800	119
Strontium	µg Sr/kg	3.2	484.0	480.8	400	120
Zirconium	µg Zr/kg	0.6	18.6	18.0	20	90
Cadmium	µg Cd/kg	<0.1	8.0	8.0	10	80
Tin	µg Sn/kg	0.1	14.5	14.4	20	72
Barium	µg Ba/kg	1.1	133	132	200	66
Mercury	µg Hg/kg	<0.1	14.2	14.3	10	143
Lead	µg Pb/kg	0.3	11.7	11.4	10	114

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